

## PATENT ABSTRACTS OF JAPAN

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**(54) PREFILLED SYRINGE**

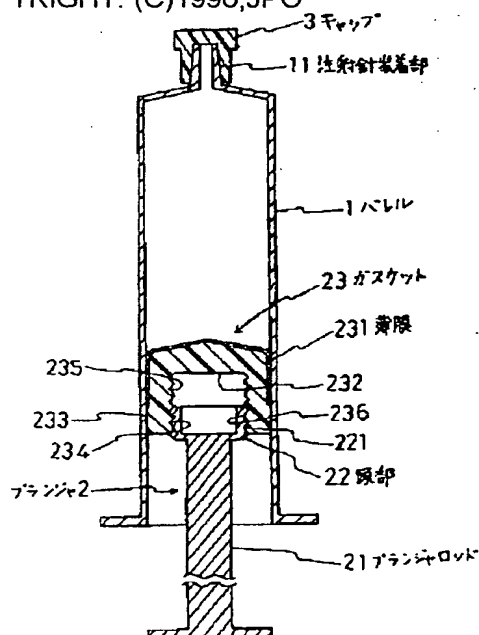
(57) Abstract:

PURPOSE: To provide a prefilled syringe wherein there exists no possibility of mixing of foreign matters and eluation and enough liq.-and air-tightness exist during storing and good sliding properties of a gasket is provided when it is used.

CONSTITUTION: A gasket 23 is formed of a rubbery elastic body and the outer diameter of a part 233 of the rear end is smaller than the inner diameter of a barrel 1 and the front face and the side face except the part 233 with the smaller outer diameter are covered with a plastic thin film 231 with good sliding properties and in addition, the inner diameter of a part 234 on the inlet side of a recessed part 232 for fixing a plunger rod is reduced. In addition, at the first position where the head part 22 of the plunger rod 21 is inserted into this part 234 with a reduced inner diameter, the part 233 with a smaller outer diameter of the gasket 23 is expanded so as to fit tightly this on the inner wall of the barrel 1 and at the second position where the

head part 22 of the plunger rod 21 is inserted into the part 235 with a inner diameter being not reduced, the part 233 with the smaller outer diameter of the gasket expanded at the first position is returned to the original outer diameter.

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3. In the drawings, any words are not translated.

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**DETAILED DESCRIPTION**

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[Detailed Description of the Invention]

[0001]

[Field of the Invention] this invention is large at the time of a store, and relates the sliding friction between a gasket and the wall of a barrel to the prefilled syringe which was made to become small at the time of use while it abolishes fear of the elution from a gasket in detail about a prefilled syringe.

[0002]

[Description of the Prior Art] The medical fluid is beforehand sealed in the glass syringe (barrel), seal of the side which connects a hypodermic needle at the time of use is canceled, a hypodermic needle is connected, and what used the rubber plate for generally sealing the medical fluid in a barrel conventionally at the hypodermic needle connection side, and used the gasket of rubber for the open end side as the syringe which enabled it to medicate a patient with a medical fluid, and the so-called prefilled syringe is known. However, since the compounding agent contained in the rubber which forms a seal member, for example, sulfur and a vulcanization accelerator, an impurity, etc. were eluted in a medical fluid at the time of a store, the prefilled syringe using such a rubber plate and the gasket of rubber as a seal member was what cannot be used for intravenous injection.

[0003] Then, coating or the syringe which carried out the laminating is proposed early in the morning as what improved the fault of elegance such conventionally in the field in contact with the medical fluid of a seal member in the thin film made from plastics other than a fluorine system resin (JP,55-32602,Y). However, this syringe uses the barrel made from glass, and the gasket made from a fluorine system resin has a problem in fluid-tight nature and airtightness by the barrel made from glass, and although it was not desirable in the disposer pull syringe which formed the barrel used abundantly in recent years by plastics in the gasket formed by plastics other than a fluorine system resin, since sliding nature will become bad if it is going to improve the fluid-tight nature between the walls of a gasket and a barrel, and airtightness, it is necessary to apply a silicone oil to a sliding fraction as lubricant. And for the medicine prescribed for the patient, a silicone oil is a foreign matter, and since it also becomes the cause of a particulate contamination, it is not desirable. Then, in order to make it what can satisfy both a gasket, the fluid-tight nature between the walls of a barrel, and airtightness and sliding nature The whole surface of the fraction in contact with the medical fluid of a seal member, and the sliding fraction with a syringe wall A tetrafluoroethylene-resin film, A laminating is carried out by one chosen out of the group which consists of ethylene, a tetrafluoroethylene-resin film, and an ultra-high-molecular-weight-polyethylene film. Furthermore, the gasket which limited the length of the contact surface of the periphery section of a gasket and the wall fraction of a barrel to the specific domain is proposed (JP,5-34669,Y).

[0004]

[Problem(s) to be Solved by the Invention] However, although it is satisfactory in using for a usual syringe, when this is used for a prefilled syringe, when a plunger is strongly pushed at the time of a store unlike adhesion with the gasket made from the rubber-elasticity field, and a barrel wall, a medical fluid may leak the gasket of aforementioned JP,5-34669,Y, and a problem is in the fluid-tight nature at the time of a store, and airtightness. this invention was made in view of the problem on \*\*, has neither mixing of a foreign matter, nor fear of elution, has fluid-tight nature and airtightness sufficient at the time of a store, and aims at offering the prefilled syringe equipped with the good gasket of sliding nature at the time of use.

[0005]

[Means for Solving the Problem] The barrel in which the back end opened the hypodermic needle insertion section wide in preparation for a nose of cam in order that this invention might solve the above-mentioned technical problem, The plunger which consists of a gasket attached at the nose of cam of a plunger rod and this plunger rod, In the prefilled syringe with which it consists of a cap closed down densely, and the interior of a barrel was beforehand filled up with the medical fluid the hypodermic needle insertion section of a barrel -- liquid -- While a gasket is formed with the rubber-elasticity field and the outer diameter of the fraction by the side of the back end is made into a minor diameter from the bore of a barrel The front face and the side face except a \*\*\*\*\* outer-diameter fraction are covered with the thin film of the good plastics of sliding nature. this -- The concavity for plunger rod attachment to which the bore of a small outer-diameter fraction and a corresponding fraction was reduced is prepared. furthermore, the rear face -- the account of an entrance-side front -- On the other hand, the plunger rod has the head which has the bore of the fraction by which the diameter of the aforementioned concavity for plunger rod attachment is not reduced, and the outer diameter of an equivalent size. This head in the 1st position inserted in the bore reduction fraction of the concavity for plunger rod attachment of a gasket Extend the outer-diameter fraction with a small gasket, and this is stuck to the wall of a barrel. In the 2nd position which inserted the head of a plunger in the fraction by which the diameter of the concavity for plunger rod attachment of a gasket is not reduced, the prefilled syringe with which the outer diameter of the outer-diameter fraction with the small gasket extended in the 1st position returns to the original outer diameter, and it comes to make it is adopted. Here, as good plastics of sliding nature, ultra high molecular weight polyethylene is desirable. While an engagement slot is established in the base of the concavity for plunger rod attachment of a gasket so that a gasket can be rotated before use, an engagement salient is prepared at the nose of cam of a head of a plunger, and an engagement salient may be made to be inserted in the 2nd position in an engagement slot.

[0006]

[Function] According to the above-mentioned configuration, when the head of a plunger rod is in the 1st position of the concavity for plunger rod attachment of a gasket, the outer diameter of the outer-diameter fraction with a small gasket is extended, it sticks to the wall of a barrel, and the seal of between the gaskets made from the rubber-elasticity field and the walls of a barrel with a large sliding friction is carried out strongly. And since the sliding friction between the gaskets made from the rubber-elasticity field and the walls of a barrel with a large sliding friction is applied to the sliding friction between the fraction covered with the thin film made from plastics of a gasket, and the wall of a barrel, the sliding friction in this position becomes very large. Therefore, since a seal is carried out by part for the fraction covered with the thin film made from plastics of a gasket, and a rubber-elasticity soma, even if a plunger is strongly pushed during a store, an internal medical fluid does not leak the space in which a plunger does not move and a medical fluid is moreover held even if a plunger is strongly pushed during a store from this fraction. next, the outer-diameter fraction with a gasket small when a plunger rod is advanced and the head is made to come to the 2nd position of the concavity for plunger rod attachment -- contracting -- the original outer diameter -- returning - - the outer diameter of the head of a plunger rod, and the bore of the concavity for plunger rod attachment in this position -- abbreviation -- since it is equal, the outer diameter of the fraction covered with the thin film made from plastics of a gasket does not change Therefore, when the sliding friction in this position is small since it was only a sliding friction between the fraction covered with the thin film of the good plastics of the sliding nature of a gasket, and the wall of a barrel, the cap of the hypodermic needle insertion section is removed and a plunger is pushed, a plunger slides smoothly.

[0007]

[Example] Next, the example of this invention is explained based on a drawing. Drawing 1 is drawing of longitudinal section of the prefilled syringe in which one example of this invention is shown, and shows the status at the time of a store. Moreover, drawing 2 is drawing showing preparation-for-use operation of the prefilled syringe of drawing 1, and drawing and the drawing 4 showing [ 3 ] the status at the time of use of the prefilled syringe of drawing 1 are a perspective diagram showing other examples of a plunger rod. As shown in drawing 1, it is covered with the

thin film 231 of the plastics with the prefilled syringe of this invention sufficient [ a front face and the side face excluding / a gasket 23 is formed with the rubber-elasticity field, and the outer diameter of the fraction 233 by the side of the back end is smaller than the bore of a barrel 1, and / the small outer-diameter fraction 233 / sliding nature ], and the bore of the fraction 234 of the entrance side of the concavity for plunger rod attachment 232 is reduced further. And in the 1st position which inserted the head 22 of the plunger rod 21 in this bore reduction fraction 234, the small outer-diameter fraction 233 of a gasket 23 is extended, this is stuck to the wall of a barrel 1, and the outer-diameter fraction 233 with the small gasket extended in the 1st position returns to the original outer diameter in the 2nd position inserted in the bore fraction 235 which is not having the diameter of the head 22 of the plunger rod 21 reduced.

[0008] A barrel 1 is the cylinder of the syringe usually formed by thermoplastics, such as polypropylene, and polyethylene, an ethylene tetracyclo dodecen copolymer, and the hypodermic needle insertion section 11 is formed at the nose of cam of a barrel 1. and -- this hypodermic needle insertion section 11 -- this fraction -- liquid -- the crown-ed of the cap 3 who is closed down densely and removed at the time of use is carried out, and he can adopt the rubber-elasticity field, polyethylene, etc. as a cap's 3 formation material Especially as rubber-elasticity field, thermoplastic elastomer, such as SEBS resin and a polyethylene system elastomer, is desirable.

[0009] Although not illustrated in a barrel 1, it fills up with the medical fluid, and the back open end side is closed by the gasket 23 of a plunger 2. The gasket 23 is formed by synthetic rubber, such as the rubber-elasticity field, for example, isobutylene isoprene rubber, and ethylene-propylene rubber, polyisoprene rubber, and thermoplastic elastomer, such as SEBS resin. It is reduced, the outer diameter of the fraction by the side of the back end of a gasket 23 has become the small outer-diameter fraction 233, and the front face and the side face of the gasket 23 except this small outer-diameter fraction 233 are covered with the ultra-high-molecular-weight-polyethylene and amount polypropylene of super-macromolecules, polytetrafluoroethylene, and ethylene-tetrafluoroethylene copolymer, the perfluoro ethylene-propylene copolymer, etc. [ of the good plastics of sliding nature ]

[0010] The concavity for plunger rod attachment 232 is formed in the rear face of a gasket 23, and it has the means (a female screw 236 is usually adopted) for combining the plunger rod 21 with the wall. The fraction 234 of the entrance side corresponding to the small outer-diameter fraction 233 of a gasket 23 in this concavity for plunger rod attachment 232, It consists of a back fraction 235 corresponding to the fraction which covered the thin film 231. The back fraction 235 is carried out, the outer diameter of the head 22 (in drawing, it has the male screw 221 in the outer wall corresponding to the female screw 236 of the concavity for plunger rod attachment 232) of the plunger rod 21 inserted in this, abbreviation, etc. are in it, it has the bore, and the bore of the fraction 234 of an entrance side is reduced. Moreover, in order that the thickness of the concavity for plunger rod attachment 232 may enlarge the sliding friction in the 1st position, the fraction 234 of an entrance side is greatly formed a little from the back fraction 235.

[0011] Although the head 22 of the plunger rod 21 is screwed on the concavity for plunger rod attachment 232 As shown in drawing 1 at the time of a store of a prefilled syringe, a head 22 is in the 1st position of the concavity for plunger rod attachment 232 (a head 22 is located in the fraction 234 of an entrance side). By extending the bore of this fraction 234, the outer diameter of the small outer-diameter fraction 233 is extended, and the outer wall of the small outer-diameter fraction 233 is strongly stuck in the outer wall of a barrel 1. On the other hand, at the time of use of a prefilled syringe, as shown in drawing 2, the housekeeping operation which rotates the plunger rod 21 and moves a head 22 to the 2nd position (a head 22 is located in the back fraction 235) is required. In this case, since the outer diameter of the small outer-diameter fraction 233 of a gasket 23 contracts and it separates from the wall of a barrel 1, the sliding friction between the wall of a barrel 1 and the outer wall of a gasket 23 becomes equal to the sliding friction between the wall of a barrel 1, and the thin film 231 of a gasket 23. and the bore of the fraction 235 in the inner part of the concavity for plunger rod attachment 232 and the outer diameter of the head 22 of the plunger rod 21 -- abbreviation -- since it is equal, the sliding friction between the wall of a barrel 1 and the thin film 231 of a gasket 23 hardly changes by the case where it is in the case where a head 22 is in the 1st position, and the 2nd position What is necessary is to attach a hypodermic needle 4 in the hypodermic needle insertion

section 11, and just to push a plunger 2 with a finger, after removing the cap 3 of the hypodermic needle insertion section 11 in case of use of a prefilled syringe, as shown in drawing 3. In addition, you may be made to engage with the engagement slot (not shown) which formed the engagement salient 222 which is shown in drawing 4 at the nose of cam of the head 22 of the plunger rod 21, and prepared this in the base of the concavity for plunger rod attachment 232 of a gasket 23.

[0012] [an example 1] -- the front face and the side face except a small outer-diameter fraction -- ultra high molecular weight polyethylene (the product made from Mitsui Petrochemical Industries \*\*) -- the gasket made from isobutylene isoprene rubber (it mms an outer diameter 9.7 --) which the film (thickness of 70micro) of 3 comes to laminate molecular weight 2,200,000 and the density of 0.935g/cm The plunger equipped with length 8.3 mm at the nose of cam is prepared, and it is a barrel made from polypropylene (capacity of 3ml, bore 9.5 mm) about this. It inserts. When the head of a plunger rod was in the 1st position of the concavity for plunger rod attachment, and the 2nd position and the sliding friction was measured, the result as shown in Table 1 was obtained. in addition, the laminate-film fraction among the side faces of a gasket -- a length -- the thickness of 4.0 mm and a concavity -- 2.9 mm -- it is -- a part for an isobutylene-isoprene-rubber outcrop -- a length -- the thickness of 2.0 mm and a concavity -- 4.1mm and an outer diameter -- 9.0mm it was. Moreover, measurement of a sliding friction was performed by crosshead speed 100mm/min using Shimazu autograph S-500-D (product made from Shimadzu \*\*).

[0013] The plunger equipped with the gasket made from isobutylene isoprene rubber which has the same outer diameter and same length as the [examples 1-2 of comparison] example 1 at the nose of cam is prepared, and it is a barrel made from polypropylene (capacity of 3ml, bore 9.5 mm) about this. It inserts. By the case where a silicone oil (KF96H10000CS, product made from Shin-Etsu Chemical \*\*) is applied to the wall of a barrel, and the case where it has not applied, when the sliding friction was measured by the same technique as an example 1, the result as shown in Table 1 was obtained.

[0014] As compared with the case where the sliding friction in case the head of a plunger rod is in the 1st position with the prefilled syringe of this invention from the result of Table 1 has not applied the silicone oil to the wall of a barrel, it is far large and the sliding friction in the case of being in the 2nd position understands that there is no difference so much with the case where the silicone oil is applied to the wall of a barrel.

[0015]

[Table 1]

	摺動抵抗値 (平均)	備考
実施例 1	5 3 4 9 g	第1の位置
実施例 1	1 4 1 g	第2の位置
比較例 1	8 8 g	シリコーンオイル塗布
比較例 2	1 3 1 0 g	シリコーンオイル無塗布

[0016]

[Effect of the Invention] The effect of being able to inject smoothly at the time of use can be done so, without a medical fluid leaking during a store, since it has fluid-tight nature and airtightness sufficient at the time of the store which is a safety since there is neither mixing of a foreign matter nor fear of elution in the medical fluid held in the interior by adopting the prefilled syringe of this invention so that clearly from having explained above and it has the good gasket of sliding nature at the time of use.

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[Translation done.]